

## REMARKS

The Office Action mailed on February 17, 2010, has been reviewed and the comments of the Examiner carefully considered. Claims 1, 5-13 and 20 are pending and currently stand rejected.

### **Double Patenting Rejections**

1. Claims 1, 11-13 and 20 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/579,897 in view of Partain. Applicants respectfully disagree with the grounds for rejection. However, for the sake of advancing prosecution, Applicants submit herewith a Terminal Disclaimer in compliance with 37 C.F.R. 1.321(c).

3. Claims 1-3 and 20 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 13 of copending Application No. 10/608,553 in view of Partain. As a preliminary matter, the Examiner indicates that this rejection was maintained from the previous Office Action. In the previous rejection, the Examiner rejected claims 1-3 and 12, not 1-3 and 20. Therefore, Applicants will address the rejection as previously levied against claims 1-3 and 12.

Applicants disagree with the grounds for rejection. To begin with, Applicants direct the Examiner's attention to the experimental examples, which demonstrate the sustained release of dye from the claimed compositions. The cited references do not demonstrate the production of such a composition.

Further, the combination of references set forth by the Examiner does not yield a wound dressing material dyed with an antioxidant dyestuff wherein the dyestuff is bound to the surface of the bioabsorbable substrate and allows sustained release of the effective amounts of the antioxidant dyestuff.

The term "dyed" as used in the instant claims refers to a solid material that has been surface-treated while in the solid state with a dye to bind the dye. Partain does not teach such a composition, nor does Partain provide any teaching, suggestion or motivation to prepare such a

material. Therefore, Partain cannot be used in conjunction with copending Application No. 10/608,553 to render the present claims obvious. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejections under 35 U.S.C. § 103(a)**

1. Claims 1, 5, 6 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Partain et al. (EP0368253) in view of Rosenthal et al. (US 5,565,210). It is the Examiner's view that the combination of the cited patents would lead one of skill in the art to arrive at claims 1, 5, 6 and 20, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. § 103 ...

[T]he four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. (MPEP § 2141).

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined. MPEP § 2141 II. This test has not been satisfied here for any of the obviousness rejections.

It is alleged in the Office Action that the Rosenthal reference equates oxidized regenerated cellulose (ORC) with chitosan. Applicants respectfully submit that there is no teaching or suggestion in Rosenthal that would lead the skilled artisan to equate chitosan with ORC. Specifically, the Office Action alleges that "oxidized cellulose is functionally equivalent

to the chitosan materials taught by Partain, a fact appreciated by the teachings of Rosenthal.” However, this conclusion does not follow from a reading of Rosenthal, and is therefore unsubstantiated and incorrect.

In fact, the Rosenthal reference distinguishes chitosan and ORC. Rosenthal discusses chitosan in the background of the invention, as a material used in a prior art patent (see col. 1, lines 50-55). Rosenthal goes on to note that “[T]he porous bioabsorbable implants that have been suggested to date are all isotropic materials...This does not conform to the reality of wound healing...” Col. 2, lines 25-35. Further on in the patent, Rosenthal mentions ORC as an optional material, in contrast to a list of materials from animal sources (see col. 3, lines 15-30). The skilled artisan, when reading Rosenthal, will – at a minimum – not find Rosenthal to equate ORC and chitosan in any manner, and most likely, will understand Rosenthal to distinguish chitosan and ORC as described above.

Partain does not correct the deficiency of Rosenthal. In fact, Partain does not teach or suggest the use of any material other than chitosan, nor does Partain equate chitosan with ORC. For example, see column 2 of Partain, which exemplifies the advantages of chitosan.

MPEP 2141 requires that “Factual findings made by Office personnel are the necessary underpinnings to establish obviousness. Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103.” (Emphasis added). These requirements have not been met in the present case. It has not been shown that the cited references provide any suggestion or motivation for equating chitosan and ORC, nor has it been shown that the references provide any teaching or suggestion as to why one of skill in the art would make such a comparison, nor what one of skill in the art would subsequently do with such a comparison. The Office Action provides no articulated nexus between the cited references and the present claims. The skilled artisan simply has no reasonable expectation of success in arriving at Applicant’s present claims by equating ORC and chitosan, as the two are separately taught in Rosenthal, and the Office Action provides no evidence to the contrary.

MPEP 2142 requires that in order to establish a *prima facie* case of obviousness, “...rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal

conclusion of obviousness.” Citing *in re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). The statements in the present Office Action, however, are merely conclusory.

As clearly set forth in MPEP 2142, “The tendency to resort to “hindsight” based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” (Emphasis added). The only way that the skilled artisan could bridge the gap between the ORC and chitosan taught in Rosenthal is by impermissibly relying upon Applicants’ presently-pending claims.

When the prior art is viewed as a whole, it is found that the references, either taken alone or in combination, do not provide any teaching or motivation for the skilled artisan to arrive at the present claims, *when the claimed invention is properly viewed as a whole*. In the present Office Action, the obviousness rejection is based on that which was disclosed for the first time in the present patent application. The rejections in the Office Action require the steps of the claims themselves in order to illustrate the alleged obviousness. Therefore, the rejection is improper and Applicants respectfully request withdrawal of the rejection.

Because the rejected claims are not obvious in view of the cited references, as set forth above, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

2. Claims 1, 5-7, 13 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Partain and Rosenthal, further in view of Fowler et al. (US 5,667,501). It is the Examiner’s view that the combination of the cited patents would lead one of skill in the art to arrive at claims 1, 5-7, 13 and 20, in their entirety. Applicants respectfully traverse the Examiner’s rejection for the following reasons.

As set forth above, Partain and Rosenthal, taken together, do not render the claims obvious. Fowler does not correct this deficiency. Fowler does not provide any teaching or suggestion that would lead the skilled artisan to equate the ORC and chitosan taught separately in Rosenthal.

Because Partain, Rosenthal and Fowler, taken together, do not provide any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the

rejected claims are obvious in view of Partain, Rosenthal and Fowler as set forth above, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 5-7, 13 and 20 are thereby allowable as written as depending from an allowable independent claim.

3. Claims 1, 5-10 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Partain, Rosenthal, and Fowler, further in view of Nimrod (WO 87/05517). It is the Examiner's view that the combination of the cited patents would lead one of skill in the art to arrive at claims 1, 5-10 and 20, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

As set forth above, Partain, Rosenthal and Fowler, taken together, do not render the claims obvious. Nimrod does not correct this deficiency. Nimrod does not provide any teaching or suggestion that would lead the skilled artisan to equate the ORC and chitosan taught separately in Rosenthal.

Because Partain, Rosenthal, Fowler, and Nimrod, taken together, do not provide any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the rejected claims are obvious in view of Partain, Rosenthal, Fowler, and Nimrod, as set forth above, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 5-10 and 20 are thereby allowable as written as depending from an allowable independent claim.

4. Claims 1, 5-12 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Partain, Rosenthal, and Fowler, further in view of Gibbins (US 6,355,858). It is the Examiner's view that the combination of the cited patents would lead one of skill in the art to arrive at claims 1, 5-12 and 20, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

As set forth above, Partain, Rosenthal and Fowler, taken together, do not render the claims obvious. Gibbins does not correct this deficiency. Gibbins does not provide any teaching

or suggestion that would lead the skilled artisan to equate the ORC and chitosan taught separately in Rosenthal.

Because Partain, Rosenthal, Fowler, and Gibbins, taken together, do not provide any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the rejected claims are obvious in view of Partain, Rosenthal, Fowler, and Gibbins, as set forth above, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 5-12 and 20 are thereby allowable as written as depending from an allowable independent claim.

**Conclusion**

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5033) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

**BREDA MARY CULLEN ET AL.**

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